

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Freeman, Gordon J et al

Serial No.: 09/425,516

Filed: October 22, 1999

For: *Novel CTLA4/CD28 Ligands And Uses Therefor*

Attorney Docket No.: RPI-004C3CN

Group Art Unit: 1644

Examiner: Gambel, P

Commissioner for Patents
Washington, D.C. 20231**Certificate of First Class Mailing (37 CFR §1.8(a))**

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August 6, 2001
Date of Signature and of Mail Deposit

By:

Meg E. Williams
Megan E. Williams, Esq.
Registration No. 43,270
Attorney for Applicants

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Applicants and their attorney are aware of the following patents, publications or other information, which are cited on the attached PTO Form 1449, and in accordance with 37 C.F.R. §1.97 hereby submit these forms for the Examiner's consideration.

The present application is a Continuation Application of U.S. Serial No. 08/479,744, filed June 7, 1995 (Atty. Docket No. RPI-004CP3), which is a Continuation-in-Part of U.S. Serial No. 08/280,757, filed July 26, 1994 (Atty Docket No. RPI-004C2CPA), which is a Continuation-in-Part of U.S. Serial No. 08/109,393, filed August 19, 1993 (Atty. Docket No. RPI-004CP), which is a Continuation-in-Part of U.S. Serial No. 08/101,624, filed July 26, 1993 (Atty. Docket No. RPI-004). U.S.

Serial Number: 09/425,51~

Page -2-

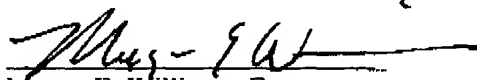
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Serial No. 08/479,744 is also a Continuation-in-Part of U.S. Serial No. 08/147,773, filed November 3, 1993 (Atty. Docket No. RPI-008). Copies of the references listed on the enclosed PTO Form 1449 have been previously cited by or submitted to the Office in the prior applications, and, in accordance with 37 C.F.R. §1.98(d), copies of these references are not enclosed herewith, but will be provided upon request. However, certain references (A4, A5, A8, A9, A15, B15, C1, D1-D6 and D13-D19) have not been previously cited, and are therefore enclosed.

This statement is not to be interpreted as a representation that the cited publications are material, that an exhaustive search has been conducted, or that no other relevant information exists. Nor shall the citation of any publication herein be construed *per se* as a representation that such publication is prior art. Moreover, Applicants understand that the Examiner will make an independent evaluation of the cited publications.

Under 37 C.F.R. § 1.97(b)(3), no additional costs are believed to be due in connection with the filing of this disclosure. If, however, a first Office Action on the merits issues in this application bearing a mailing date prior to the date of this Information Disclosure Statement, please charge the appropriate fee as required under 37 CFR §1.17(p) to our Deposit Order Account No. 12-0080.

Respectfully submitted,
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APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-80 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO RPI-004C3CN	SERIAL NO 09/425,516
LIST OF PUBLICATIONS CITED BY APPLICANT (Use several sheets if necessary)	APPLICANT Freeman, Gordon J. et al.	
	FILING DATE October 22, 1999	GROUP 1644

U S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	A1	5116964	05/92	Capon et al	536	23 5	
	A2	5434131	07/95	Linsley et al	514	2	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	A3	WO 93/00431	01/93	PCT				
	A4	WO 94/12520	06/94	PCT				
	A5	WO 95/03408	02/95	PCT				
	A6	WO 95/05464	02/95	PCT				
	A7	WO 95/06738	03/95	PCT				

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

	A8	Azuma, M. et al., "B70 antigen is a second ligand for CTLA-4 and CD28," <i>Nature</i> 366:76-79 (1993)
	A9	Azuma, M. et al., "Involvement of CD28 in MHC-unrestricted cytotoxicity mediated by a human natural killer leukemia cell line," <i>J Immunol.</i> 149(4):1115-1123 (1992)
	A10	Baskar, S. et al. (1993) "Constitutive Expression of B7 Restores Immunogenicity of Tumor Cells Expressing Truncated Major Histocompatibility Complex Class II Molecules" <i>Proc. Natl. Acad. Sci. USA</i> 90:5687-5690
	A11	Bateman, W J et al (1991) "Inducibility of Class II Major Histocompatibility Complex Antigens by Interferon γ Is Associated with Reduced Tumorigenicity in C3H Mouse Fibroblasts Transformed by v-Ki-ras" <i>J. Exp. Med.</i> 173 193-196
	A12	Blazar, B.R., "In vivo blockade of CD28/CTLA4: B7/BB1 interaction with CTLA4-Ig reduces lethal murine graft-versus-host disease across the major histocompatibility complex barrier in mice," <i>Blood</i> 83(12):3815-3825 (1994)
	A13	Boussiotis, V.A. et al. (1993) "Activated Human B Lymphocytes Express Three CTLA-4 Counterreceptors that Costimulate T-Cell Activation" <i>Proc Natl. Acad. Sci. USA</i> 90: 11059-11063
	A14	Chen, L. et al. (1992) "Costimulation of Antitumor Immunity by the B7 Counterreceptor For the T Lymphocyte Molecules CD28 and CTLA-4" <i>Cell</i> 71:1093-1102
	A15	Classon et al., "The hinge region of the CD8 alpha chain structure, antigenicity, and utility in expression of immunoglobulin superfamily domains," <i>Int. Immunol.</i> 4(2):215-225 (1992)
	A16	Clements, V.K. et al. (1992) "Invariant Chain Alters The Malignant Phenotype of MHC Class II ⁺ Tumor Cells" <i>J. of Immunology</i> 149:2391-2396
	A17	Cole, G.A. et al. (1991) "Rejection of Allogeneic Tumor Is Not Determined by Host Responses to MHC Class I Molecules and is Mediated By CD4 ⁺ CD8 ⁺ T Lymphocytes That Are Not Lytic for the Tumor" <i>Cellular Immunology</i> 134 480-490
Examiner		Date Considered
*EXAMINER Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		

Sheet 2 of 4

APPLICANT FACSIMILE OF FORM PTO-1449 REV 7-88	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO RPI-004C3CN	SERIAL NO 09/425,516
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FOREIGN PATENT DOCUMENTS

	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

	B1	Fearon, E.R. et al. (1990) "Interleukin-2 Production By Tumor Cells Bypasses T Helper Function in the Generation of An Antitumor Response" <i>Cell</i> 60:397-403
	B2	Freedman, A. S. et al. (1987) "B7, A B Cell-Restricted Antigen That Identifies Preactivated B Cells" <i>Journal of Immunology</i> 139(10) 3260-3267
	B3	Freeman et al., "Structure, Expression, and T Cell Costimulatory Activity of the Murine Homologue of the Human B Lymphocyte Activation Antigen B7" <i>Journal Experimental Medicine</i> , vol. 174, pp. 625-631, (1991)
	B4	Freeman, G. J. et al. (1989) "B7, A New Member of the Ig Superfamily with Unique Expression on Activated and Neoplastic B Cells" <i>Journal of Immunology</i> 143(8): 2714-2722
	B5	Freeman, G., et al., "Cloning of B7-2; A CTLA-4 Counter-Receptor that Costimulates Human T Cell Proliferation," <i>Science</i> , vol. 262, 909-911 (1993)
	B6	Galvin, F. et al. (1992) "Murine B7 Antigen Provides A Sufficient Costimulatory Signal For Antigen-Specific and MHC-Restricted T Cell Activation" <i>J. Immunology</i> 149 3802-3808
	B7	Gimmi et al., "B-cell surface antigen B7 provides a costimulatory signal that induces T cells to proliferate and secrete interleukin 2" <i>Proceedings of the National Academy of Sciences</i> , vol. 88, pp. 6575-6579, (1991)
	B8	Gimmi, C., et al., "Human T-cell Clonal Anergy is Induced by Antigen Presentation in the Absence of B7 Costimulation," <i>Proc Natl Acad. Sci. USA</i> , vol. 90, 6586-6590 (1993)
	B9	Guo, Y. et al. (1995) "Mutational Analysis and an Alternatively Spliced Product of B7 Defines Its CD28/CTLA4-binding Site on Immunoglobulin C-like Domain" <i>J. Exp. Med.</i> , 181 1345-1355
	B10	Harding, F. and Allison, J., "CD28-B7 Interactions Allow the Induction of CD8 sup + Cytotoxic T Lymphocytes in the Absence of Exogenous Help," <i>J. Exp. Med.</i> , vol. 177, 1791-1796 (1993)
	B11	Harding, F., et al., "CD28-mediated Signalling Co-stimulates Murine T Cells and Prevents Induction of Anergy in T-cell Clones," <i>Nature</i> , vol. 356, 607-609 (1992)
	B12	Hollenbaugh and A. Aruffo (1992) "Construction of Immunoglobulin Fusion Proteins" <i>Immunology Suppl.</i> 4, Unit 10 19 1-11
	B13	Inobe, M. et al. (1994) "Identification of an Alternatively Spliced Form of the Murine Homologue of B7", <i>Biochemical and Biophysical Research Communication</i> 200(1):443-449
	B14	James, R.F.L. "The effect of class II gene transfection on the tumorigenicity of the H-2K-negative mouse leukaemia cell line K36.16," <i>Immunology</i> , 1991 Feb, 72(2) 213-8
	B15	June, C.H. et al., "The B7 and CD28 receptor families," <i>Immunol Today</i> , 1994 Jul, 15(7) 321-31
Examiner		Date Considered
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DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

C1	Lanier, L.L. et al., "CD80 (B7) and CD86 (B70) provide similar costimulatory signals for T cell proliferation, cytokine production, and generation of CTL," <i>J. Immunol.</i> 1995 Jan 1;154(1):97-105	
C2	Lenschow, D.J. et al., "Expression and functional significance of an additional ligand for CTLA-4," <i>Proc. Natl. Acad. Sci. U. S. A.</i> 1993 Dec 1;90(23):11054-8	
C3	Lenschow, D.J. et al., "Long-term survival of xenogeneic pancreatic islet grafts induced by CTLA4lg," <i>Science</i> , 1992 Aug 7;257(5071):789-92	
C4	Linsley, P.S. et al., "Immunosuppression in vivo by a soluble form of the CTLA-4 T cell activation molecule," <i>Science</i> , 1992 Aug 7;257(5071) 792-5	
C5	Linsley, P.S. et al., "Binding of the B cell activation antigen B7 to CD28 costimulates T cell proliferation and interleukin 2 mRNA accumulation," <i>J. Exp. Med.</i> , 1991 Mar 1;173(3):721-30	
C6	Lin, H. et al., "Long-term acceptance of major histocompatibility complex mismatched cardiac allografts induced by CTLA4lg plus donor-specific transfusion," <i>J. Exp. Med.</i> , 1993 Nov 1;178(5):1801-6	
C7	Nabavi, N. et al., "Signalling through the MHC class II cytoplasmic domain is required for antigen presentation and induces B7 expression," <i>Nature</i> 1992 Nov 19;360(6401):266-8	
C8	Ostrand-Rosenberg, S. et al., "Costimulation through murine B7 molecule restores immunogenicity of autologous tumor cells expressing truncated MHC class II molecules," <i>J. Cell Biochem. Suppl. (Abstract HZ 228)</i> (1993) p. 71	
C9	Ostrand-Rosenberg, S. et al., "Abrogation of tumorigenicity by MHC class II antigen expression requires the cytoplasmic domain of the class II molecule," <i>J. Immunol.</i> , 1991 Oct 1;147(7):2419-22	
C10	Ostrand-Rosenberg, S. et al., "Rejection of mouse sarcoma cells after transfection of MHC class II genes," <i>J. Immunol.</i> , 1990 May 15;144(10):4068-71	
C11	Reiser, H. et al., "Murine B7 antigen provides an efficient costimulatory signal for activation of murine T lymphocytes via the T-cell receptor/CD3 complex," <i>Proc. Natl. Acad. Sci. U. S. A.</i> , 1992 Jan 1;89(1):271-5	
C12	Schultz, K. et al., "The role of B cells for in vivo T cell responses to a Friend virus-induced leukemia," <i>Science</i> , 1990 Aug 24;249(4971) 921-3	
C13	Schwartz, "A cell culture model for T lymphocyte clonal anergy," <i>Science</i> 1990 Jun 15;248(4961):1349-56	
C14	Southern, S.O. et al., "Induction of the H-2 D antigen during B cell activation," <i>J. Immunol.</i> 1989 Jan 1;142(1):336-42	
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APPLICANT FACSIMILE OF FORM PTO-1448 REV 7-00	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY DOCKET NO RPI-004C3CN	SERIAL NO 09/425,516
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	D1	5,434,141	07/95	Schafer et al.	514	53	
	D2	5,747,034	05/98	De Boer et al.	424	137.1	
	D3	5,770,197	06/98	Linstey et al	424	134.1	
	D4	5,869,050	02/99	De Boer et al.	424	156.1	
	D5	6,071,716	06/00	Freeman et al	435	69.1	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
	D6	WO 92/00092	01/92	PCT			

OTHERS (including Author, Title, Date, Pertinent Pages, Etc.)

	D7	Tan, P. et al. "Induction of alloantigen-specific hyporesponsiveness in human T lymphocytes by blocking interaction of CD28 with its natural ligand B7/BB1." <i>J. Exp. Med.</i> 1993;177(1):165-73
	D8	Townsend, S.E. et al. (1993) "Expression of the T cell costimulatory ligand B7 by a melanoma induces rejection mediated by direct activation of CD8+ T cells." <i>J Cell Biochem Supp.</i> 136 (abstr.)
	D9	Townsend, S. E. et al. "Emergency hospital admissions and readmissions of patients aged over 75 years and the effects of a community-based discharge scheme," <i>Health Trends</i> 1992;24(4):136-9
	D10	Townsend, S. E. et al., "Tumor rejection after direct costimulation of CD8+ T cells by B7-transfected melanoma cells," <i>Science</i> , 1993 Jan 15;259(5093):368-70
	D11	Travis, J. "A stimulating new approach to cancer treatment," <i>Science</i> 1993 Jan 15;259(5093) 310-1
	D12	Van der Bruggen, P. et al., "A gene encoding an antigen recognized by cytolytic T lymphocytes on a human melanoma," <i>Science</i> 1991 Dec 13;254(5038):1643-7
	D13	Chen, C., et al., "Monoclonal Antibody 2D10 Recognizes a Novel T Cell Costimulatory Molecule on Activated Murine B Lymphocytes", <i>J Immunol.</i> 152: 2105-2114 (1994).
	D14	P, Engel, et al., "The B7-2 (B70) Costimulatory Molecule Expressed by Monocytes and Activated B Lymphocytes Is the CD86 Differentiation Antigen, <i>Blood</i> , Vol. 84(5) 1994: pp 1402-1407
	D15	Freeman, G., et al., "Murine B7-2, an Alternative CTLA4 Counter-receptor that Costimulates T Cell Proliferation and Interleukin 2 Production", <i>J. Exp. Med.</i> 178: 2185-2192 (1993);
	D16	Freeman, G., et al., "Uncovering of Functional Alternative CTLA-4 Counter-Receptor in B7-Deficient Mice", <i>Science</i> 262: 907-909 (1993).
	D17	Hathcock, K., et al., "Identification of an Alternative CTLA-4 Ligand Costimulatory for T Cell Activation", <i>Science</i> 262: 905-907 (1993);
	D18	Nozawa et al., A Novel Monoclonal Antibody (FUN-1) Identifies An Activation Antigen In Cells of The B-Cell Lineage and Reed-Sternberg Cells, <i>Journal of Pathology</i> , Vol. 169:309-315 (1993)
	D19	Powers, G., et al., "Expression and Functional Analysis of Murine B7 Delineated by a Novel Monoclonal Antibody", <i>Cell. Immunol.</i> 153: 298-311 (1994).

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